REMARKS

In the present Office Action, claims 1-38 were examined. Claims 1-38 are rejected, no claims are objected to, and no claims are allowed.

By this Amendment, claims 1, 6, 7, 10, 13, 20, 21, 22, 23, 24, 28, 29 and 31 have been amended, claims 5 and 14 have been canceled, and no claims have been added. Accordingly, claims 1-4, 6-13 and 15-38 are presented for further examination. No new matter has been added. By this Amendment, claims 1-3, 6-13 and 15-38 are believed to be in condition for allowance.

Finality of the rejection should be withdrawn.

In making this final rejection, the Examiner applied to new references, Hess et al. (U.S. patent No. 6,196,219) and Poley et al. (U.S. Patent No. 6,418,924). These two references were not mentioned at all in the previous Office Action.

The Examiner, in paragraph 20 of the present Office Action, stated that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action." Applicants respectfully take issue with that conclusion. Independent claim 1 was amended previously only to change the word "apparatus" to - - device - - . This was to correct antecedent basis for the latter and the scope of claim 1 was not affected. Accordingly, the new rejection of claim 1, and certain dependent claims over Hess et al. cannot properly be made a final rejection.

Likewise, claim 12 (dependent upon claim 1) and claim 16 (dependent upon claim 13) were not amended at all. Thus, there is no basis to say the application of new reference Poley et al. was the result of Applicant's amendments. Clearly, this finality of the present Office Action should be withdrawn.

Explanation of Above Amendments

The above-noted amendments to the specification are merely to include reference to new Fig. 6, which was requested by the Examiner in paragraph 2 of the present Office Action. No new matter is believed to be included or intended by these amendments.

The amendments to claims 1 and 21 are to show that the electronic data carrier is separate from the drug vials.

The amendments to claims 6, 7, 10 and 29 are to make minor grammatical changes. No change in the scope of the claim is intended.

The amendments to claims 13 and 26 are made to better describe the position of the electric input vis-à-vis the medication center.

The amendment to claims 22, 23, 24 and 28 are made to better describe the claimed treatment submission portion and the data center.

The amendments to claim 31 are made to better describe this method of prescribing a drug.

Rejections/Objections under 35 USC §112

The Examiner objected to claim 5 under 35 U.S.C. §112, second paragraph, as being of improper dependent form. This objection has been rendered moot by the above withdrawal of claim 5.

Rejections under 35 USC §102

The Examinc newly and finally rejected claims 1-8, 13, 14, 18, 20 and 21 under 35 U.S.C. §102(b) as being anticipated by Hess et al. (U.S. Patent No. 6,196, 219). Applicant respectfully traverses this final rejection for the following reasons. In Hess et al., the magazine which is inserted into the device contains a number of multidose inhalers (MDI's). In other words, the magazine includes a number of different drug delivery devices. In Figure 1 of Hess et al. the magazine includes eight liquid droplet spray

devices. Although the magazine fits within an inhaler body 1, it is not that body which creates the liquid droplet, but the liquid droplet spray devices 5 within the magazine. Thus, the magazine 28 not only includes the liquid droplet spray devices, a reservoir (which might correspond with the vials in claims 1 and 21), but also includes a non-volatile memory means 29.

In contrast, amended claims 1 and 21 state that the electronic data carrier is separate from the drug vials. This is substantially different from what is shown in Hess et al. because in Hess et al. it is a unitary magazine including all of these components together. The non volatile memory 29 is not separate from the reservoirs 3 of the liquid droplet spray devices 5. This distinction is of great significance because the present invention does not relate to a multi dose inhaler. The drug package has a number of drug vials which are individually poured into the drug delivery device since they typically contain a unit dose. The electronic data carrier must be separate from the drug vials since it is used in conjunction with the drug delivery device for each of the treatments delivered by the drug within a vial. This is additionally important where a drug must be constituted immediately before it is poured into the drug delivery device, typically by mixing two substances together to create the final drug. Such a drug cannot be delivered in an MDI type inhaler of the type shown in Hess et al. because that device relies on the drug being created in its final form when it is manufactured. Thus, it will be understood that the fact that the data carrier is separate from the drug vials is of great significance and is distinct from Hess et al. It would not be obvious to separate the non volatile memory means in Hess et al. from the magazine since the magazine is a unitary construction. There is no incentive for a skilled person to separate the two.

Furthermore, claims 13 and 20 have been amended to include the feature of a medication chamber as part of the drug delivery apparatus as well as an electronic input

arranged remotely from the medication chamber for receiving treatment information from the data carrier. None of the prior art teaches or suggests such an arrangement. This further emphasizes the fact that the data carrier and vials must be separate. In claim 13, the electronic input is arranged remotely from the medication chamber to make it clear that the source of electronic data is different from the container from which the medication is poured into the medication chamber.

Rejections under 35 USC §103

The Examiner finally rejected claims 9-11 as being obvious in view of Hess et al. (U.S. Patent No. 6,196,219), taken in view of Rode et al (U.S. Patent 6,315,719). Applicant respectfully traverses this rejection for the following reasons. The above remarks concerning the deficiencies of Hess et al. are equally applicable here. Rode et al. does not overcome those deficiencies.

The Examiner also newly and finally rejected claims 12, 16 and 19 as being obvious and unpatentable over Hess et al. (U.S. Patent 6,196,219), taken in view of Poley et al. (U.S. Patent No. 6,418,924) applicant respectfully traverses this rejection for the following reasons:

The above remarks concerning the deficiencies of Hess et al. are equally applicable here. The teachings of Poley et al. do not overcome those deficiencies.

Further, the Examiner finally and newly rejected claim 17 as being obvious and unpatentable over Hess et al., taken in view of Wolf et al. (U.S. Patent No. 5,505,195). Applicant respectfully traverses this rejection for the following reasons:

The above remarks concerning the deficiencies of Hess et al. are equally applicable here. The teachings of Wolf et al. do not overcome those deficiencies.

And still further, the Examiner finally rejected claims 22 to 38 as being obvious and unpatentable over Wolf et al. (U.S. Patent No. 5,505,195), taken in view of Eigler et al. (U.S. patent No. 6,328,699). Applicant respectfully traverses this rejection for the following reasons:

Amended claims 22 to 38 are directed to either a system or process whereby, on the basis of analysis in the claimed data center, either the patient is referred to a doctor for treatment, or if the specifications are met, a repeat prescription is generated.

The point that a repeat prescription is automatically generated when the measured specifications are met is a critical feature of this embodiment of the present invention. Basis for this can be found on page 15, lines 468 to 472.

In contrast, neither Wolf et al. or Eigler et al. discloses such a direct dispensing of a prescription or drug. In the Wolf et al. patent, the doctor conducts the analysis, and in Eigler et al. the initial information is provided first to the patient to change his therapy in response to signals. The patient must then get a new prescription. Eigler et al. also suggests in column 10, lines 60 to 65 that any analysis will be conducted when the information is sent back to the hospital doctor or pharmacy. Neither of the prior art documents discloses what is disclosed in the flow chart of Figure 5 where the data analysis and protocol is conducted at a data center prior to requesting more medication from a pharmacy or contacting a doctor. Thus, the present invention provides an effective automatic service to these customers where a doctor or a pharmacy does not have to analyze the data directly.

Accordingly, Applicant submits that none of the references, alone or in combination, anticipate or make obvious the invention as presently claimed and that the application is now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and further examination of the application and the Examiner is

respectfully requested to take such proper actions so that a patent will issue herefrom as soon as possible.

If the Examiner has any questions or believes that a discussion with Applicant's attorney would expedite prosecution, the Examiner is invited and encouraged to contact the undersigned at the telephone number below.

Please apply any credits or charge any deficiencies to our Deposit Account No. 23-1665.

Respectfully submitted,
Jonathan Stanley Harold Denyer, et al.

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